UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMAG PHARMACEUTICALS, INC., Plaintiff, v. AMERICAN GUARANTEE AND LIABILITY INSURANCE COMPANY, Defendant.	)	Civil Action No. 1:21-cv-10618-MJJ

MEMORANDUM OF DECISION

August 16, 2024

JOUN, D.J.

On April 13, 2021, plaintiff AMAG Pharmaceuticals, Inc. ("AMAG") filed suit against its insurer, defendant American Guarantee and Liability Insurance Company ("AGLIC"), alleging AGLIC wrongly denied coverage for losses incurred by AMAG in November and December 2017. [Doc. No 1]. AMAG claims breach of contract and seeks declaratory judgment regarding its entitlement to coverage under its insurance policy with AGLIC. [*Id*. at ¶¶ 69-82].

On December 22, 2023, AGLIC filed a Motion for Summary Judgment on all counts. [Doc. No. 122]. The matter was fully briefed, and a hearing was held on April 2, 2024. [Doc. No. 142]. For the reasons set forth below, AGLIC's Motion for Summary Judgment is GRANTED.

I. BACKGROUND

A. Relevant Facts

1. The McPherson Facility

AMAG is a pharmaceutical company based in Waltham, Massachusetts. [Doc. No. 140 at ¶ 1]. In November and December 2017, AMAG owned the rights to sell Makena®, an injectable drug prescribed to certain women to reduce the risk of preterm birth. [*Id*. at ¶ 11]. AMAG contracted with a third-party supplier, Pfizer, Inc. ("Pfizer"), to manufacture Makena® at Pfizer's facility in McPherson, Kansas ("the McPherson facility"). [*Id*. at ¶ 14].

Pfizer manufactured Makena® in a room called the "M6 filling area" or "M6 line" or "M6 Filling Room," in the McPherson Facility. [*Id*. at ¶ 16]. The M6 Filling Room, referred to as a "clean room," is intended to be a Grade A, aseptic pharmaceutical manufacturing space with environmental conditions designed to maintain product sterility [*Id*. at ¶¶ 17-18]. The room is used to fill vials with either (1) liquid-filled product; or (2) lyophilized (or freeze-dried) product. [*Id*. at ¶ 19]. The room contains a machine called the "M6 Trayer," which is used in the manufacture of lyophilized products only. [*Id*. at ¶¶ 21-22]. Makena® is a liquid-filled product, thus the M6 Trayer is not used in its manufacture. [*Id*. at ¶¶ 20, 23]. The M6 Trayer uses "rake arms" to gather vials of lyophilized product into trays while the product is partially stoppered. [*Id*. at ¶ 24]. The rake arms are powered by compressed air. [*Id*. at ¶ 26].

Additionally, during the manufacture of pharmaceutical products, the M6 Filling Room uses equipment that produces a "laminar airflow," meaning that filtered air is blown down into the clean room from the ceiling and flows consistently from top to bottom over the equipment used in the clean room. [*Id*. at ¶ 81]. The filtered air is then captured by an air vent in the floor—it is not recirculated in the room. [*Id*. at ¶ 82].

2. The Air Leak and Resolution

On November 9, 2017, Pfizer conducted maintenance activity in the M6 Filling Room. [Doc. No. 140 at ¶ 27]. The maintenance work order from November 9, 2017 identified no issues or concerns with a compressed air line. [*Id*. at ¶ 44].

On November 10, 2017, environmental monitoring alarms activated in the M6 Filling Room, indicating that non-viable particulates (NVPs) had been detected in the room. [*Id*. at ¶ 109]. The root cause of the alarms was not immediately identified, and Pfizer's Senior Production Operators for the M6 Filling Room opened multiple panels of the M6 Trayer and performed troubleshooting for over 17 hours. [*Id*. at ¶ 110; Doc. No. 125-1 at 9; Doc. No. 125-12 at 11]. Eventually, on November 12, 2017 at 12:05 a.m., Pfizer determined that there was a leak of filtered compressed air to one of M6 Trayer's lyophilized rake arms. [Doc. No. 125-1 at 9]. By 12:26 a.m., the air leak was resolved. [*Id*. at 9-10].

The parties dispute the nature and extent of the issue with the M6 Trayer's compressed air line. Oscar Sanchez, AMAG's then-VP of Quality, testified that the only way the air leak could have occurred was if part of the air line had been broken off. [Doc. No. 134-1 at 26]. He stated that the compressed air lines on the M6 Trayer were "swaged air lines," permanently connected such that "[t]here's no coming loose. It's impossible. It's swaged on. The only way for it to come loose is for it to break off." [*Id*.; *see also* Doc. No. 140 at ¶ 108]. Mr. Sanchez never saw the air line at issue or any photos of the air line, and he does not know what the line or the connection to that line looks like. [Doc. No. 134-1 at 26-27]. Mr. Sanchez testified that the basis for his opinion was a conversation with a Pfizer employee who told him the air line had broken, as well as "lots of years of experience on a production floor and dealing with the same things"

and the fact that the damage alleged based on "a slightly loose connection that somebody just went in there and tightened" did not "make sense" to him [*Id*. at 27-29].

On the other hand, Pfizer's corporate representative, Lisa Thimmesch, personally participated in Pfizer's subsequent Risk Assessment investigation. [Doc. No. 125-2 at 6, 16]. She did not note any "swaged air lines" when describing how the air line was connected to the M6 Trayer, but rather testified that a "bolt actually holds [the] compressed air-line quick connect to the tray mechanism." [*Id.* at 12, 32-33]. Ms. Timmesch also testified that no one at Pfizer ever said or wrote that the air line "either came apart or broke apart," nor did she ever see such a statement from anyone else, and Pfizer did not identify any damage to or replace the bolt, the quick-connect fitting, or the air line in resolving the air leak. [*Id*. at 13-14]. The only action taken by Pfizer to address the air leak was to tighten the bolt on the air line quick connect. [*Id*. at 13, 33]. Pfizer's post-incident Risk Assessment Report and its Response to FDA Form 483 also do not describe any "swaged air lines." *See generally* [Doc. No. 125-1; Doc. No. 125-4]. Pfizer's report states, "Once the air leak was detected, a third open panel intervention was performed to tighten the bolt on the air-line quick connect attachment to Rake Arm #1 of M6 trayer. Tightening of the bolt on 11-12-17 successfully resolved the air leak and addressed the non-viable EMS alarms." [Doc. No. 125-1 at 9]. Pfizer likewise noted to the FDA that "[t]he air leak was the result of a loose fitting. It was later determined that the loose fitting was the result of a maintenance activity that took place the day prior (09Nov2017); this precipitated the initial NVP alarm failure. … The leak was remediated at 00:26 hours on 12Nov2017…" [Doc. No. 125-4 at 5]. AMAG's technical expert, Mark Robbins, after examining a photo of the air line, testified, "I believe from the information I have—as I said, apparently tightening that bolt resolved [the air

leak]," and that the tightening of the bolt is the only repair he was aware of that Pfizer did. [Doc. No. 135-4 at 30, 38].

Sanitation using isopropyl alcohol was performed after each open panel intervention. [Doc. No. 125-1 at 10]. Between November 10, 2017 and December 8, 2017, all room and line sanitizations were performed as required per procedure, through the application of disinfectants such as isopropyl alcohol, Sporklenz, and NaOCl (also known as bleach). [*Id*. at 11-12].

3. Mold and Shutdown

It was discovered that there was mold on the M6 Trayer, and that the air leak had caused mold to be blown into the air above the M6 Trayer in the M6 Filling Room. [Doc. No. 140 at ¶¶ 77, 118; Doc. No. 125-1 at 5; Doc. No. 125-4 at 5, 8]. From December 9, 2017, through January 20, 2018, Pfizer stopped all manufacturing activities in the M6 Filling Room. [Doc. No. 140 at ¶¶ 120, 133]. Pfizer's Risk Assessment report notes:

> "[T]he origin of the mold is from the compressed air or from within the Lyo trayer cabinet which was disturbed as a result of the air leak. The investigation cannot definitively conclude if the source of the mold was from the air leaked into the cabinet or from the equipment within the cabinet. However, the data clearly indicates that this mold was localized to the trayer area and did not impact the area until the compressed air began to leak on 11-10-17."

[Doc. No. 125-1 at 5; Doc. No. 140 at ¶ 121].

During a planned shutdown of the McPherson facility in the summer of 2017, Pfizer had undertaken multiple "engineering projects" and "process improvements," including the addition of a stainless steel skirting to the bottom of the M6 Trayer. [Doc. No. 140 at ¶ 76]. AGLIC asserts that the steel skirting negatively affected airflow and that, "[b]ecause the steel skirting was sealed to the floor, an air leak in the M6 Trayer area would force air to be pushed back up, along with any [mold] particles already existing there." [*Id*. at ¶¶ 83-85].

Prior to the shutdown, Pfizer had manufactured four lots of Makena®, on November 17 and 25 and December 2 and 7, 2017. [Doc. No. 140 at ¶ 132]. Following a risk assessment, Pfizer ultimately determined that it would not release those four lots of Makena®. [*Id*. at ¶¶ 135, 60; Doc. No. 125-4 at 6]. AMAG alleges that the non-delivery of the four lots resulted in more than $30 million net revenue loss to AMAG, plus other covered losses. [Doc. No. 1 at ¶ 36].

4. The Policy

AMAG purchased from AGLIC an all-risk insurance policy, Policy No. ERP0088480-02 ("the Policy"), for the policy period of February 1, 2017, to February 1, 2018. [Doc. No. 140 at ¶¶ 2, 94]. The Policy provides coverage for property damage, business interruption (referred to in the Policy as "Time Element"), and contingent business interruption, among other covered causes and types of loss. [*Id*. at ¶ 94]. The Policy provides up to $265,000,000 in total coverage, including up to $50,000,000 for contingent business interruption loss. [*Id*. at ¶¶ 100-01].

Per the Insuring Agreement, the Policy "insure[s] against direct physical loss of or damage caused by a Covered Cause of Loss to Covered Property, at an Insured Location described in Section II-2.01, all subject to the terms, conditions, and exclusions stated in this Policy." [*Id*. at ¶ 3; Doc. No. 1-1 at 14]. The Policy defines "Covered Cause of Loss" as "[a]ll risks of direct physical loss of or damage from any cause unless excluded." [Doc. No. 140 at ¶ 4; Doc. No. 1-1 at 60].

As noted, the Policy provides business interruption coverage "during the Period of Liability," provided the loss "result[s] from the necessary Suspension of the Insured's business activities at an Insured Location." [Doc. No. 140 at ¶ 5; Doc. No. 1-1 at 26]. The Policy's contingent business interruption provision extends this coverage to reach business income losses resulting from direct physical loss of or damage to dependent properties. [Doc. No. 140 at ¶ 7;

Doc. No. 1-1 at 33]. The McPherson facility is a covered property under the Policy. [Doc. No. 140 at ¶¶ 15, 99]. "For building and equipment," the Period of Liability is limited to:

> The period starting from the time of physical loss or damage of the type insured against and ending when with due diligence and dispatch the building and equipment could be repaired or replaced, and made ready for operations under the same or equivalent physical and operating conditions that existed prior to the damage.

[Doc. No. 140 at ¶ 6; Doc. No. 1-1 at 26].

The Policy contains certain exclusions from coverage. The Policy's Contamination Exclusion provides:

> This Policy excludes the following unless it results from direct physical loss or damage not excluded by this Policy.
>
> > Contamination, and any cost due to Contamination including the inability to use or occupy property or any cost of making property safe or suitable for use or occupancy, except as provided by the Radioactive Contamination Coverage of this Policy."

[Doc. No. 140 at ¶ 8; Doc. No. 1-1 at 23]. The Policy defines "Contamination (Contaminated)" as "[a]ny condition of property due to the actual presence of any foreign substance, impurity, pollutant, hazardous material, poison, toxin, pathogen or pathogenic organism, bacteria, virus, disease causing or illness causing agent, Fungus, mold or mildew." [Doc. No. 140 at ¶ 9; Doc. No. 1-1 at 60].

The Policy also contains a faulty workmanship and defective design exclusion, which "excludes the following but any resulting physical damage not otherwise excluded is insured: Faulty, inadequate or defective design, specifications, workmanship, construction or materials used." [Doc. No. 140 at ¶ 10; Doc. No. 1-1 at 24].

B. Procedural History

In June 2018, AMAG provided notice of its insurance claim to AGLIC. [Doc. No. 140 at ¶ 137]. AGLIC initially denied coverage for the claim in September 2018, but then agreed to

continue investigating AMAG's claim on December 20, 2018, January 5, 2019, and June 12, 2019. [Doc. No. 1 at ¶ 41]. During its investigation, AGLIC retained technical consultant Philip Platcow of Vertex Engineering. [Doc. No. 140 at ¶ 88]. Mr. Platcow wrote a report stating that "the airline [*sic*] was subsequently repaired and the production line was placed back in service." [*Id*. at ¶ 90; Doc. No. 125-13 at 9]. Mr. Platcow has testified that he did not undertake any independent investigation of the events giving rise to this action and that, in his report, he was "simply reviewing the report that Pfizer provided and, you know, parroting that information back." [Doc. No. 125-14 at 33]. He stated, "I know that there was an air leak at a loose bolt. And that that was tightened and successfully solved the issue with the environmental monitoring alarm going off." [*Id*.] Relying on Mr. Platcow's findings, AGLIC reasserted its coverage denial on January 15, 2021, and again on March 30, 2021. [Doc. No. 1 at ¶ 42].

AMAG filed its Complaint on April 13, 2021, asserting a claim for breach of contract and a claim for a declaratory judgment that its losses are covered under the Time Element, Contingent Time Element, and Professional Fees coverage provisions. [Doc. No. 1 at ¶¶ 69-82]. On December 22, 2023, AGLIC moved for Summary Judgment on both counts. [Doc. No. 122].

II. LEGAL STANDARD

Summary judgment is appropriate when, based upon the pleadings, affidavits, and depositions, "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

Generally, "a party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). "To succeed, the moving party must show that there is an absence of evidence to support the nonmoving party's position." *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990). Once it has made the requisite showing, the burden shifts to the nonmovant to "present definite, competent evidence to rebut the motion" and demonstrate that a "trialworthy issue persists." *Vineberg v. Bissonnette*, 548 F.3d 50, 56 (1st Cir. 2008) (internal citations and quotations omitted). "'[T]he mere existence of a scintilla of evidence' is insufficient to defeat a properly supported motion for summary judgment." *Torres v. E.I. Dupont De Nemours & Co.*, 219 F.3d 13, 18 (1st Cir. 2000) (quoting *Anderson*, 477 U.S. at 252). Further, the party opposing summary judgment may not rely on—and the Court may not consider—"conclusory allegations, improbable inferences, acrimonious invective, or rank speculation." *Clarendon Nat'l Ins. Co. v. Philadelphia Indem. Ins. Co.*, 954 F.3d 397, 404 (1st Cir. 2020). Rather, the "party opposing summary judgment must present definite, competent evidence to rebut the motion." *Maldonado–Denis v. Castillo–Rodriguez,* 23 F.3d 576, 581 (1st Cir. 1994). In making this assessment, the court "must view the entire record in the light most hospitable to the party opposing summary judgment, indulging in all reasonable inferences in that party's favor." *Griggs–Ryan v. Smith,* 904 F.2d 112, 115 (1st Cir. 1990).

III. ANALYSIS

AGLIC asserts that AMAG's coverage claims suffer from three independent infirmities: (1) AMAG's alleged losses are not covered because they were not caused by any "direct physical loss of or damage to" property; (2) any coverage for business income losses is precluded by the

Policy's Contamination Exclusion; and (3) any coverage is also precluded by the Policy's exclusion for faulty workmanship and defective design. [Doc. No. 123 at 6-7].

As to the first assertion, AMAG responds that its losses were caused by physical loss of or damage to Pfizer's property in three ways: (1) the M6 Trayer sustained physical damage through a broken air line; (2) the M6 Filling Room sustained physical damage through the compressed air leakage and mold contamination; and (3) Pfizer suffered physical loss of the M6 Filling Room when the air leak temporarily "caused that facility to be no longer aseptic and unable to be used for its intended purpose of manufacturing pharmaceuticals." [Doc. No. 132 at 15-20]. For the reasons set forth below, AMAG's three theories fail, and there is no genuine dispute as to the lack of direct physical loss of or damage to Pfizer's property. And where the Policy thus does not apply to provide coverage, discussion of either the contamination exclusion or the faulty workmanship and defective design exclusion is not necessary.

A. Physical Damage or Loss to the M6 Trayer

AGLIC asserts that the air leak occurred when a bolt attached to an air line of the M6 Trayer came loose and that the air leak was resolved once the bolt was tightened, such that there was no physical damage or repair. [Doc. No. 123 at 6-7]. AMAG, however, contends that the air line of the M6 Trayer was broken and required repair, such that there was physical damage to the M6 Trayer. [Doc. No. 132 at 11-12]. In support of its position, AMAG points to four pieces of evidence, among others: testimony from AMAG's then-Vice President of Quality, Mr. Sanchez, that the air line broke and that it would be "impossible" for the air line to "come loose" due to its swagelock construction; Pfizer's disclosure to the FDA that the M6 Trayer required "repair" after the compressed air incident; Pfizer's corporate designee's testimony that the M6 Trayer

underwent "repair"; and the fact that Pfizer conducted three open-panel interventions over a 17-hour period on the M6 Trayer. [*Id*. at 16].

Mr. Sanchez's testimony is not based on first-hand knowledge of the M6 Trayer, as he never saw the air line or connection at issue, whether in person or through photographs. [Doc. No. 134-1 at 26-27]. The only bases for his opinion were a conversation he had with a Pfizer employee, his "lots of years of experience on a production floor and dealing with the same things," and his opinion that the damage alleged based on "a slightly loose connection that somebody just went in there and tightened" simply did not "make sense." [*Id*. at 27-29]; *supra* at 3-4. Mr. Sanchez's speculative, hearsay testimony cannot create a factual dispute to defeat summary judgment. *See Hannon v. Beard*, 645 F.3d 45, 49 (1st Cir. 2011) ("It is black-letter law that hearsay evidence cannot be considered on summary judgment for the truth of the matter asserted.") (cleaned up)); Fed. R. Civ. P. 56(c)(2) ("A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence."); *Irobe v. United States Dep't of Agric.*, 890 F.3d 371, 381 (1st Cir. 2018) ("A court need not take at face value a party's subjective beliefs, even if offered in the form of testimony, if those subjective beliefs are conclusory, self-serving, and lack factual support in the record." (cleaned up)). And while Pfizer and other witnesses may have used the word "repair" in their reports and testimony, the record is clear that the "repair" refers only to the tightening of a loose fitting—a repair which took over 17 hours to discover, but which only took 21 minutes to implement. *See, e.g.*, [Doc. No. 125-4 at 5; Doc. No. 125-1 at 7, 9; Doc. No. 125-2 at 12-13].

Accordingly, the record evinces only that the air leak occurred due to a loosened bolt in the M6 Trayer and that the air leak was resolved once the bolt was tightened. The question, then,

is whether the loose bolt constitutes physical loss or damage, such that the Policy applies here. I find that it does not.

The Policy covers "direct physical loss of or damage to" property, which the SJC has held to require "some distinct, demonstrable, physical ***alteration*** of the property." *Verveine Corp. v. Strathmore Ins. Co.*, 489 Mass. 534, 542 (2022) (cleaned up) (emphasis added); *see also Legal Sea Foods, LLC v. Strathmore Ins. Co.*, 36 F.4th 29, 34 (1st Cir. 2022). The M6 Trayer was not altered by the loosened bolt; indeed, a bolt is designed in function to be loosened and tightened. By analogy, if one were to use a garden hose with a sprayer nozzle, and water leaked from the hose as a result of a loosened nozzle, the water leak would be resolved by tightening and closing that nozzle—as intended by design. The hose would not have sustained a distinct, demonstrable, physical alteration in that situation, and an "objectively reasonable insured," *W. All. Ins. Co. v. Gill*, 426 Mass. 115, 117 (1997), would not reasonably make a claim for damage related to the loosened nozzle and leak. Just so for the bolt and M6 Trayer here. No action beyond the tightening of the bolt was needed to remediate the air leak. There was no damage to the bolt, the quick-connect fitting, or the air line, nor were any of these parts replaced. *See, e.g.*, [Doc. No. 125-2 at 13]. A loose bolt does not constitute "direct physical loss of or damage to" property.

B. <u>Physical Damage to the M6 Filling Room</u>

Notwithstanding, AMAG further contends that there existed "additional physical damage to the clean room that required extensive repair and remediation." [Doc. No. 132 at 13]. In so arguing, AMAG focuses on the compressed air that leaked into the room from the air line and potentially pushed up and distributed mold above the M6 Trayer. The First Circuit, however, has rejected the proposition that the circulation of an airborne contaminant is evidence of physical

damage to property. *See Legal Sea Foods, LLC*, 36 F.4th at 34–35 ("[W]hile saturation, ingraining, or infiltration of a substance into the materials of a building or persistent pollution of a premises requiring active remediation efforts is sufficient to constitute 'direct physical loss of or damage to property,' evanescent presence of a harmful airborne substance that will quickly dissipate on its own, or surface-level contamination that can be removed by simple cleaning, does not physically alter or affect property, and, thus, is not likewise sufficient." (cleaned up)).

While true that compressed air "is a physical force," [Doc. No. 132 at 17], AMAG offers no record evidence that the discharge of compressed air physically damaged the M6 Filling Room by physically altering or affecting the property. Nor can AMAG claim that the air leak dispersed mold and caused physical damage to the room. Due to the laminar airflow produced in the M6 Filling Room, filtered air blows from top to bottom over the equipment in the room and is then captured by an air vent in the floor—it is not recirculated into the room. [Doc. No. 140 at ¶ 81-82]. The parties do not allege that, absent the air leak, any mold-contaminated air could have been forced into the room; as such, the only period that mold could have polluted the M6 Filling Room is from when the air leak commenced on November 10, 2017 to when it was resolved via the tightening of the bolt on November 12, 2017. But there is no evidence of mold found anywhere outside of the M6 Trayer, no evidence of mold in the Makena® lots or elsewhere in the M6 Filling Room, and evidence that Pfizer only conducted routine cleaning with surface cleaning agents following resolution of air leak, [Doc. 125-1 at 11-12]. In other words, the record contains no evidence of mold dispersal or physical damage resulting from the air leak. Indeed, the very lack of "active repair or remediation measures to correct the claimed damage" evinces the lack of physical damage or loss. *Verveine Corp.*, 489 Mass. at 543 (finding that the presence of the COVID-19 virus on property, which can be remediated by "simple cleaning," fails to

constitute "direct physical loss of or damage to" property"); *cf. Matzner v. Seaco Ins. Co.*, No. 96-cv-0498, 1998 WL 566658, at *1 (Mass. Super. Ct. Aug. 12, 1998) (finding "direct physical loss or damage" where remediation efforts to resolve carbon monoxide contamination involved removing piping in chimney, lining the chimney, and installing a fan on its top). As such, where AMAG claims physical damage to the M6 Filling Room via compressed air or dispersed mold, the argument fails.

C. Physical Loss to the Room

Finally, AMAG argues that Pfizer suffered direct physical loss of the M6 Filling Room because it temporarily lost its ability to use that room for its intended purpose of manufacturing pharmaceuticals. But it is now well-established that "direct physical loss" "clearly require[s] a direct, physical deprivation of possession." *Verveine Corp.*, 489 Mass. at 545 (rejecting loss of use interpretation "without any physical alteration to accompany it" (cleaned up)); *see also, e.g.*, *BN Farm LLC v. Cincinnati Cas. Co.*, 560 F. Supp. 3d 455, 478 (D. Mass. 2021) ("Massachusetts law interprets the phrase as implicating a loss "to a tangible object, such as the structure of a building." (citations omitted)); *Legal Sea Foods*, 523 F.Supp.3d at 152 (holding direct physical loss requires "some kind of tangible, material loss."). Mere inability to use a room thus does not amount to direct physical loss of the room.[1] Moreover, the Policy expressly excludes "[l]oss or damage arising from … *loss of use*." [Doc. No. 1-1 at 23]. This exclusion straightforwardly applies to bar the loss of use claim asserted by AMAG here. *See BN Farm*, 560 F. Supp. 3d at 479 (applying exclusion for "loss of use" to "plaintiffs' allegations regarding the 'loss of functionality' of the insured premises").

[1] Notably, the record reflects that Pfizer *did* continue to manufacture pharmaceutical products in the M6 Filling Room following the air leak incident, until the shutdown in December 2017. That most of the manufactured products were ultimately not released does not change that fact.

Because the record is clear that AMAG's claimed business losses were not caused by any "direct physical loss of or damage to" Pfizer's property, and there is no genuine dispute of material fact to the contrary, the Policy does not apply to grant coverage. AGLIC is entitled to summary judgment on AMAG's claims.

IV. CONCLUSION

For the above reasons, AGLIC's Motion for Summary Judgment is GRANTED.

SO ORDERED.

/s/ Myong J. Joun
United States District Judge